

PTO-1390 (Rev. 07-2005)

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**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO. PCT/US2004/011812	INTERNATIONAL FILING DATE 16 April 2004	ATTORNEY'S DOCKET NUMBER 532552000102
		U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/553,373
TITLE OF INVENTION COMPOSITIONS FOR DELIVERY OF DRUG COMBINATIONS		
APPLICANT(S) FOR DO/EO/US Paul TARDI et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))           <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ul> </p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).           <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ul> </p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))           <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ul> </p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
<p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. (3 pages)</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13/er.2 and 37 CFR 1.821 – 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

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<p>The following fees have been submitted</p> <table border="1"> <tr> <td>21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) .....</td> <td>\$300</td> <td>CALCULATIONS</td> <td>PTO USEONLY</td> </tr> <tr> <td>22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....</td> <td>\$0</td> <td>\$</td> <td></td> </tr> <tr> <td>All other situations .....</td> <td>\$200</td> <td></td> <td></td> </tr> <tr> <td>23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....</td> <td>\$0</td> <td>\$</td> <td></td> </tr> <tr> <td>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....</td> <td>\$100</td> <td></td> <td></td> </tr> <tr> <td>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....</td> <td>\$400</td> <td></td> <td></td> </tr> <tr> <td>All other situations.....</td> <td>\$500</td> <td></td> <td></td> </tr> <tr> <td><b>TOTAL OF 21, 22 and 23 =</b></td> <td><b>\$ 0.00</b></td> <td></td> <td></td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(l)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.</td> <td colspan="2"></td> </tr> <tr> <td>Total Sheets</td> <td>Extra Sheets</td> <td>Number of each additional 50 or fraction thereof (round up to a whole number)</td> <td>RATE</td> </tr> <tr> <td>- 100 =</td> <td>/50 =</td> <td></td> <td><b>x \$250.00</b></td> </tr> <tr> <td colspan="2">Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).</td> <td>\$</td> <td></td> </tr> <tr> <td>CLAIMS</td> <td>NUMBER FILED</td> <td>NUMBER EXTRA</td> <td>RATE</td> </tr> <tr> <td>Total claims</td> <td>- 20 =</td> <td></td> <td>x</td> </tr> <tr> <td>Independent claims</td> <td>- 3 =</td> <td></td> <td>x</td> </tr> <tr> <td colspan="2">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+ 360.00</td> <td></td> </tr> <tr> <td colspan="3"><b>TOTAL OF ABOVE CALCULATIONS =</b></td> <td><b>\$ 0.00</b></td> </tr> <tr> <td colspan="3"><input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.</td> <td>0.00</td> </tr> <tr> <td colspan="3"><b>SUBTOTAL =</b></td> <td><b>\$ 0.00</b></td> </tr> <tr> <td colspan="3">Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).</td> <td>\$</td> </tr> <tr> <td colspan="3"><b>TOTAL NATIONAL FEE =</b></td> <td><b>\$ 0.00</b></td> </tr> <tr> <td colspan="3">Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +</td> <td>\$</td> </tr> <tr> <td colspan="3"><b>TOTAL FEES ENCLOSED =</b></td> <td><b>\$ 0.00</b></td> </tr> <tr> <td colspan="3"></td> <td>Amount to be refunded: \$</td> </tr> <tr> <td colspan="3"></td> <td>Amount to be charged \$</td> </tr> </table>			21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) .....	\$300	CALCULATIONS	PTO USEONLY	22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....	\$0	\$		All other situations .....	\$200			23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....	\$0	\$		Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....	\$100			International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....	\$400			All other situations.....	\$500			<b>TOTAL OF 21, 22 and 23 =</b>	<b>\$ 0.00</b>			<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(l)). 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- A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ 0.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. A duplicate copy of this sheet is enclosed.
- Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

**NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.**

SEND ALL CORRESPONDENCE TO:

/Kate H. Murashige/

SIGNATURE

Kate H. Murashige  
MORRISON & FOERSTER LLP  
12531 High Bluff Drive  
Suite 100  
San Diego, California 92130-2040  
(858) 720-5112

Kate H. Murashige

NAME

CUSTOMER NUMBER: 25225

29,959

REGISTRATION NUMBER

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/553,373	INTERNATIONAL APPLICATION NO. PCT/US2004/011812	ATTORNEY'S DOCKET NUMBER 532552000102
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I hereby certify that this paper is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EM 057522242 US, on the date shown below in an envelope addressed to: MS PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: August 7, 2007

Signature:

(Lenay Rogus)

Please type a plus sign (+) inside this box → 

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>UTILITY PATENT APPLICATION TRANSMITTAL</b> <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>		Attorney Docket No. 532552000120
		First Inventor Paul TARDI, et al.
		Title COMPOSITIONS FOR DELIVERY OF DRUG COMBINATIONS
		Express Mail Label No. EV 042154285 US

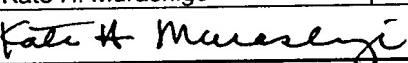
<b>APPLICATION ELEMENTS</b>		<b>ADDRESS TO:</b>																					
<i>See MPEP chapter 600 concerning utility patent application contents.</i>																							
1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17) <i>(Submit an original, and a duplicate for fee processing)</i> 2. <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. 3. <input checked="" type="checkbox"/> Specification [Total Pages 83]		7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) 8. Nucleotide and/or Amino Acid Sequence Submission <i>(if applicable, all necessary)</i> <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> Computer Readable Form (CRF)</li> <li>b. Specification Sequence Listing on:           <ul style="list-style-type: none"> <li>i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> paper</li> <li>c. <input type="checkbox"/> Statements verifying identity of above copies</li> </ul> </li> </ul>																					
4. <input type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets <input type="checkbox"/> ] 5. Oath or Declaration [Total Pages <input type="checkbox"/> ] <ul style="list-style-type: none"> <li>a. <input type="checkbox"/> Newly executed (original or copy)</li> <li>b. <input type="checkbox"/> Copy from a prior application (37 CFR 1.63(d))  <i>(for continuation/divisional with Box 18 completed)</i> <ul style="list-style-type: none"> <li>i. <input type="checkbox"/> <b>DELETION OF INVENTOR(S)</b>            Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).</li> </ul> </li> </ul>																							
6. <input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 <table border="1" style="float: right; width: 150px; margin-left: 10px;"> <tr><td colspan="2" style="text-align: center;">ACCOMPANYING APPLICATIONS PARTS</td></tr> <tr> <td>9. <input type="checkbox"/></td> <td>Assignment Papers (cover sheet &amp; document(s))</td> </tr> <tr> <td>10. <input type="checkbox"/></td> <td>37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney  <i>(when there is an assignee)</i></td> </tr> <tr> <td>11. <input type="checkbox"/></td> <td>English Translation Document <i>(if applicable)</i></td> </tr> <tr> <td>12. <input type="checkbox"/></td> <td>Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations</td> </tr> <tr> <td>13. <input type="checkbox"/></td> <td>Preliminary Amendment</td> </tr> <tr> <td>14. <input checked="" type="checkbox"/></td> <td>Return Receipt Postcard (MPEP 503)  <i>(Should be specifically itemized)</i>            Certified Copy of Priority Document(s)</td> </tr> <tr> <td>15. <input type="checkbox"/></td> <td><i>(if foreign priority is claimed)</i></td> </tr> <tr> <td>16. <input type="checkbox"/></td> <td>Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i).            Applicant must attach form PTO/SB/35 or its equivalent.</td> </tr> <tr> <td>17. <input type="checkbox"/></td> <td>Other: <input type="text"/></td> </tr> </table>				ACCOMPANYING APPLICATIONS PARTS		9. <input type="checkbox"/>	Assignment Papers (cover sheet & document(s))	10. <input type="checkbox"/>	37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney <i>(when there is an assignee)</i>	11. <input type="checkbox"/>	English Translation Document <i>(if applicable)</i>	12. <input type="checkbox"/>	Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations	13. <input type="checkbox"/>	Preliminary Amendment	14. <input checked="" type="checkbox"/>	Return Receipt Postcard (MPEP 503) <i>(Should be specifically itemized)</i> Certified Copy of Priority Document(s)	15. <input type="checkbox"/>	<i>(if foreign priority is claimed)</i>	16. <input type="checkbox"/>	Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.	17. <input type="checkbox"/>	Other: <input type="text"/>
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17. <input type="checkbox"/>	Other: <input type="text"/>																						

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

 Continuation  Divisional  Continuation-in-part (CIP) of prior application No.: 10/264,538

Prior application information: Examiner To be assigned Group / Art Unit: 1614

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number or Bar Code Label		 <b>25225</b>		or <input checked="" type="checkbox"/> Correspondence address below	
Name	Kate H. Murashige (29, 959) Morrison & Foerster LLP				
Address	3811 Valley Centre Drive, Suite 500				
City	San Diego	State	California	Zip Code	92130
Country	United States	Telephone	(858) 720-5112	Fax	(858) 720-5125
Name (Print/Type)	Kate H. Murashige		Registration No. (Attorney/Agent)	29,959	
Signature			Date	April 2, 2003	

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# FEE TRANSMITTAL for FY 2003

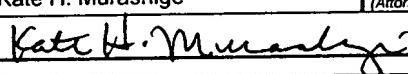
Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

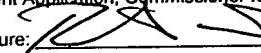
TOTAL AMOUNT OF PAYMENT (\$ 375.00)

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	Herewith
First Named Inventor	Paul TARDI, et al.
Examiner Name	Not Yet Assigned
Group Art Unit	Not Yet Assigned
Attorney Docket No.	532552000120

METHOD OF PAYMENT (check all that apply)				FEE CALCULATION (continued)																																																																																																																																																																																																	
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<input checked="" type="checkbox"/> Deposit Account				<table border="1"> <thead> <tr> <th>Large Entity</th> <th>Small Entity</th> </tr> </thead> <tbody> <tr> <td>Fee Code</td> <td>Fee (\$)</td> <td>Fee Code</td> <td>Fee (\$)</td> </tr> <tr> <td>1051</td> <td>130</td> <td>2051</td> <td>65</td> <td colspan="2">Surcharge – late filing fee or oath</td> </tr> <tr> <td>1052</td> <td>50</td> <td>2052</td> <td>25</td> <td colspan="2">Surcharge – late provisional filing fee or cover sheet.</td> </tr> <tr> <td>1053</td> <td>130</td> <td>1053</td> <td>130</td> <td colspan="2">Non-English specification</td> </tr> <tr> <td>1812</td> <td>2,520</td> <td>1812</td> <td>2,520</td> <td colspan="2">For filing a request for ex parte reexamination</td> </tr> <tr> <td>1804</td> <td>920*</td> <td>1804</td> <td>920*</td> <td colspan="2">Requesting publication of SIR prior to Examiner action</td> </tr> <tr> <td>1805</td> <td>1,840*</td> <td>1805</td> <td>1,840*</td> <td colspan="2">Requesting publication of SIR after Examiner action</td> </tr> <tr> <td>1251</td> <td>110</td> <td>2251</td> <td>55</td> <td colspan="2">Extension for reply within first month</td> </tr> <tr> <td>1252</td> <td>410</td> <td>2252</td> <td>205</td> <td colspan="2">Extension for reply within second month</td> </tr> <tr> <td>1253</td> <td>930</td> <td>2253</td> <td>465</td> <td colspan="2">Extension for reply within third month</td> </tr> <tr> <td>1254</td> <td>1,450</td> <td>2254</td> <td>725</td> <td colspan="2">Extension for reply within fourth month</td> </tr> <tr> <td>1255</td> <td>1,970</td> <td>2255</td> <td>985</td> <td colspan="2">Extension for reply within fifth month</td> </tr> <tr> <td>1401</td> <td>320</td> <td>2401</td> <td>160</td> <td colspan="2">Notice of Appeal</td> </tr> <tr> <td>1402</td> <td>320</td> <td>2402</td> <td>160</td> <td colspan="2">Filing a brief in support of an appeal</td> </tr> <tr> <td>1403</td> <td>280</td> <td>2403</td> <td>140</td> <td colspan="2">Request for oral hearing</td> </tr> <tr> <td>1451</td> <td>1,510</td> <td>1451</td> <td>1,510</td> <td colspan="2">Petition to Institute a public use proceeding</td> </tr> <tr> <td>1452</td> <td>110</td> <td>2452</td> <td>55</td> <td colspan="2">Petition to revive – unavoidable</td> </tr> <tr> <td>1453</td> <td>1,300</td> <td>2453</td> <td>650</td> <td colspan="2">Petition to revive - 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SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Kate H. Murashige	Registration No. (Attorney/Agent)	29,959	Telephone	(858) 720-5112
Signature		Date	April 2, 2003		

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Application No. (if known):Not yet assigned

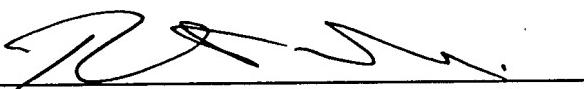
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Application Data Sheet